REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

A. Status of the Claims and Claim Amendments

As a result of the present amendment, claims 1, 3-18 and 20-26 are presented for further prosecution. Claims 25 and 26 have been added.

Claims 1 and 14 have been amended by this amendment to include a further limitation that the core is film coated to a weight gain of from about 1 to about 5% by weight. Support for these amendments can be seen, for example, from the 1st paragraph on page 5 of the specification.

Claims 25 and 26 have been added to further define the weight gains. Support to this amendment can be seen, for example, in the first paragraph of page 5 of the specification.

No new matter was added by the amendments.

B. Claims Rejections under 35 U.S.C. § 103

The Examiner rejected the subject matter of claims 1-8, 11- 24 as being unpatentable over Nellhaus in view of Sullivan; rejected Claim 9 over Nellhaus and Sullivan in view of Siegel; and rejected Claim 10 over Nellhaus in view of Johnson.

For the following reasons, it is respectfully submitted that the prior art does not teach that the core is film coated to a weight gain of from about 1 to about 5% by weight prior to a printed or etched marking being applied thereto as required in Claims 1 and 14.

1. <u>Nellhaus does not teach the limitation of the "film coated" core having a "weight gain of 1-5%".</u>

Nellhaus relates to a bar code schema for identification of solid form drugs, such as pills, tablets, capsules and the like by using a data matrix coding. It does not teach or suggest that the core be "film coated prior to the printed or etched marking being applied" and there is no teaching or suggestion in Nellhaus for a weight gain of 1-5% by weight in such a film coated core.

2. <u>Sullivan does not relate to film coating technologies</u>

The Examiner indicated on Page 7 of the Office Action that Sullivan teaches "film coated core", citing Sullivan's disclosure in Colum 11:

> *"It is preferred that the machine-readable bar code is printed onto a code-receiving layer made from a protein based film, such as keratin and gelatin, which is, in turn, adhered to the surface of the pill, preferably using water."*

The Examiner further stated that "film coating doesn't have to involve coating the whole body of the core/substrate and especially, it is noted that such limitation (coating the whole substrate) is not in the claim". Applicants consider this statement as an invitation for further clarification of the concept of the wording in the claims and respectfully submitted a copy of the relevant sections in a leading text book to clarify that the tablet film coating necessarily involves coating the whole surface of the core tablet. Please see attached copy of the Pages 145-147 from *Pharmaceutical Production Facilities: Design and Applications* by Graham Cole (Published by Informa Health Care, 1998 ISBN 0748404384, 9780748404384).

It is well know that film coating involves a coating enveloping the whole substrate. As shown in Figure 9.1 of the attached Page 146, the coating covers the whole tablet. In Figure 9.2, the spray coating gun applies the coating solution to the tablet cores without discrimination of any part

of the surface, which results in a whole film enveloping the entire substrate. The advantage of the film coating, comparing with the sugar coating, is that the film covers the whole core is thin and the weight gain of the coated tablet is very small.

In contrast, it is clear from a thorough reading of Sullivan that, the "film" mentioned in the Examiner's citation refers to a labeling "carrier", which covers only a part of the core rather than a film coating applied to the entire core substrate. The following teachings in Sullivan support this position (see 2nd paragraph of column 12):

> *"The code pattern is either printed directly on the pill, or is first printed on a carrier or code-receiving layer, as described above, such as paper, thin plastic film (e.g., PVOH or EVOH), a protein-based material, such as gelatin and keratin film or related collagen-based films, or a biocompatible polymeric sheet or film. The carrier is then preferably applied to the pill during the manufacturing process, as described above, or at a later time, perhaps by a doctor, nurse, or pharmacist, depending on the specific application of the invention."*

Clearly, the "film" in Sullivan is a sheet material which first receives the printed code and then is applied to the pill/core at a later time. This is totally different from the recited film coating as in the present invention.

Therefore, Sullivan's "code-receiving layer" is not a film coated on the pill and Sullivan does not teach the core to be "film coated prior to the printed or etched marking being applied" as recited in Claim 1 or the step of "film coating said core" prior to applying a readable printed or etched covert marking as recited in Claim 14.

3. Sullivan does not teach "weight gains" on a film coated substrate.

As mentioned in the attached section of the leading text book, film coating substrate results in a small increase in the tablet weight. To further distinguish from Sullivan, Applicants have

amended claims 1 and 14 to recite a further limitation that the "core is film coated to a weight gain of from about 1 to about 5% by weight".

According to Sullivan, if the pills are non-coated tablets, or are otherwise porous and/or have a chalk-like exterior surface, a "patch" of a non-absorbent bio-compatible material is first (or simultaneously) applied to a predetermined location on the exterior surface of the pill. The code is then directly applied to the non-absorbent patch. (see 2nd Paragraph, Column 13, Sullivan). Hence, Sullivan teaches its film as a pre-formed patch applied to a predetermined part of the surface of the pill. In fact, in Sullivan, the pill itself is never film coated and there is no weight gain mentioned for the substrate.

Therefore, Sullivan does not teach the core to be "film coated prior to the printed or etched marking being applied" as recited in Claim 1 or the step of "film coating said core" prior to applying a readable printed or etched covert marking as recited in Claim 14.

Further, Seigel and Cruttenden do not remedy the above deficiency in Nellhaus and/or Sullivan. The differences between the claimed invention and the combination of the teachings of Nellhaus, Sullivan, Johnson and/or Seigel are not obvious to a person of ordinary skill in the art at the time the claimed invention was made, as required to maintain an obviousness rejection under 35 U.S.C. § 103(a).

Applicants respectfully submitted amended Claim 1 and Claim 14 are patentable over the cited references, stand alone or in combination. Claims 3-13 and 24 are dependent claims based on Claim 1 and claims 15-18, 20-24 and 26 are directly or indirectly dependent on Claim 14. These dependent claims are patentable over the cited references as well. It is urged that all the claims patentably distinguish over all of the 35 U.S.C. § 103 rejections made by the Examiner.

C. Fees

No further fees are believed to be due. If, on the other hand, it is determined that further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

D. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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Tablet Coating Systems

'Would you tell me, please,' said Alice, a little timidly, 'why you are painting those roses?'

Five and Seven said nothing, but looked at Two. Two began, in a low voice, 'Why, the fact is, you see Miss, this here ought to have been a red rose-tree, and we put a white one in by mistake; and if the Queen was to find it out, we should all have our heads cut off, you know?'

This would appear to be a very good reason for painting anything (film-coating is a painting process) and while the penalty for coating tablets the wrong colour is unlikely to be so extreme, the Queen (FDA, MCA, etc.) is likely to extract very costly and damaging retribution. No doubt 'heads would roll' metaphorically. So why are tablets coated? After all, it is a messy, complicated and expensive process.

'Look out now, Five! Don't go splashing paint over me like that!'

'I couldn't help it,' said Five, in a sulky tone. 'Seven jogged my elbow.'

It adds a degree of risk to the production process that could result in the whole batch being rejected. The costs in terms of space, personnel, equipment, quality control and validation are considerable.

The modern coating technique has developed over the years from the use of sugar to provide a pleasant taste and attractive appearance to tablets which were unpleasant to swallow due to their bitterness. There are, of course, many forms of coating which have a special function (such as enteric coating to delay the release of the drug until it reaches the intestine), but here the simple case will be examined. First, to answer the question 'Why are tablets coated?', a number of reasons can be suggested, some not quite so obvious as others:

- The core contains a substance which imparts a bitter taste in the mouth or has an unpleasant odour.
- The core contains a substance which is unstable in the presence of light and subject to atmospheric oxidation, i.e. a coating is added to improve stability.
- The core is pharmaceutically inelegant.

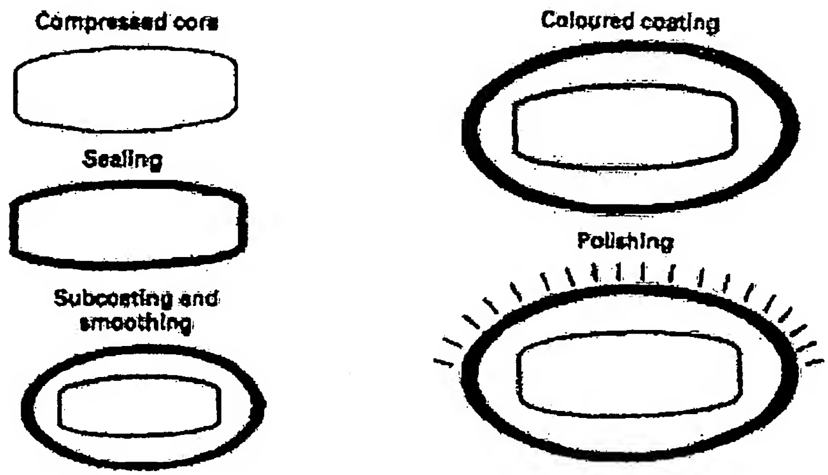

Figure 9.1 The stages in sugar coating

- The active substance is coloured and migrates easily to stain patients' clothes and hands.
- The coated tablet is packed on a high-speed packaging unit. The coating reduces friction and increases the production rate.
- To modify the drug release profile, e.g. enteric coating, sustained release coating, osmotic pumps, etc.
- Separates incompatible substances by using the coat to contain one of them or coating a pellet which is subsequently compressed into a core before coating.

This is not an extensive list but suggests several reasons for coating tablets. The process can be broken down into three main groups and one minor section:

- Sugar-coating
- Film-coating
- Particulate/pellet coating
- Compression coating.

There are several other historical coating processes such as pearl coating and pill coating which will not be discussed here.

With the exception of compression coating these processes rely on the continual application of sugar or a polymeric material to the tablet core as it rotates in a coating pan or is suspended in a fluidized cushion of air to build up micrometre thick layers. Detailed information relating to these materials can be found in *Pharmaceutical Coating Technology* (Cole *et al.*, 1995).

In the last 25 years tablet coating has undergone several fundamental changes. Coating of tablets and pills is one of the oldest techniques available to the pharmacist, and references can be traced as far back as 1838. The sugar-coating process was regarded as more of an art than a science, and its application and technology remained secret and in the hands of very few. Although a very elegant

product was obtained its main disadvantage was the processing time which could last up to five days. Many modifications were advocated to improve the basic process such as air suspension techniques in a fluidized bed, the use of atomizing systems to spray on the sugar-coating, the use of aluminium lakes of dyes to improve the evenness of colour, and more efficient drying systems. However, the process remained complicated. Generally the sugar-coating process resulted in the weight of the tablet being doubled, but the use of spraying systems enabled this increase to be reduced dramatically. The two coating processes, sugar and film are schematically represented in Figures 9.1 and 9.2.

The first reference to tablet film-coating appeared in 1930, but it was not until 1954 that Abbott Laboratories produced the first commercially available film-coated tablet. This was made possible by the development of a wide variety of materials, for example the cellulose derivatives. One of the most important of these is hydroxypropyl methylcellulose which is prepared by the reaction of methyl chloride and propylene oxide with alkali cellulose. It is generally applied in solution in organic solvents at a concentration of between 2 and 4% w/v: the molecular weight fraction chosen gives a solution viscosity of 5×10^{-2} Ns/m^2 at these concentrations.

Many advantages can be cited for film-coating in place of the traditional sugar-coating process:

1. Reduction in processing time, savings in material cost and labour.
2. Only a small increase in the tablet weight.
3. Standardization of materials and processing techniques.
4. The use of non-aqueous coating solutions and suspensions.

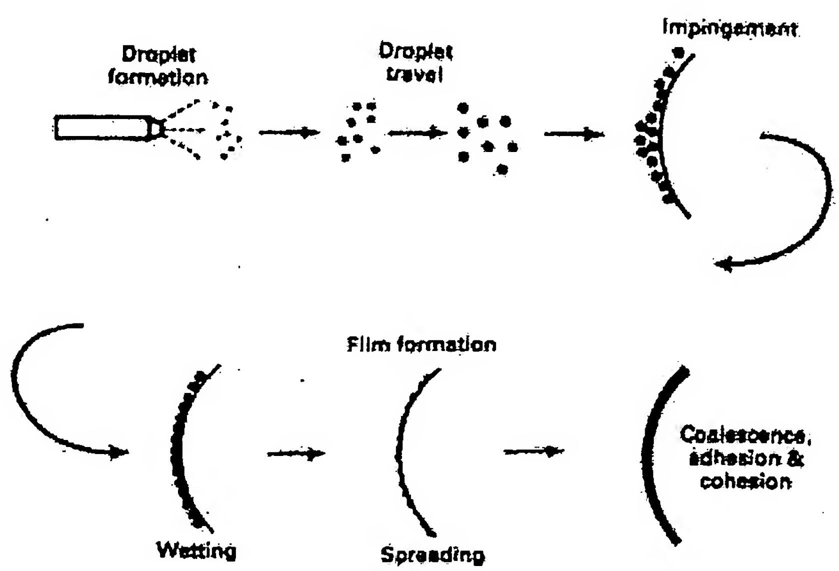

Figure 9.2 Schematic representation of the stages in spray film-coating